

c.) Remarks

The claims have been amended in order to recite the present invention with the specificity required by statute. No new matter has been added.

The claims are rejected under 35 U.S.C. §112, first and second paragraphs, as failing to comply with the written description requirement and as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner's bases for these rejections are set forth at paragraphs 2 and 4 (at pages 2 and 3) of the Office Action.

As the Examiner is aware, scientific classification utilizes, in order, the following categories, among others.

Class	
	Subclass
Order	
	Suborder
Family	
	Subfamily
Genus	
Species	

In response, Applicants wish to point out that the genus *Hydrangea* is sometimes placed in the family *Saxifragaceae*. By the same token, the genus *Hydrangea* is sometimes placed in the family *Saxifrage*, which is a common name for several members (i.e., sub-family) of the family *saxifragaceae*. The specification has been amended accordingly.

Additionally, the Examiner states it is unclear which fraction or product is responsible for improving liver function. The claims have been amended in order to

address these concerns as well. In that regard, the method of the present invention generally comprises (1) extracting a plant with an aqueous medium and filtering the resulting extract to remove the filtrate and obtain an extract residue, and (2) extracting the extract residue with alcohol or water containing alcohol to obtain an extract. That extract obtained by extracting the extract residue in step (2) is the final product (active ingredient having liver function protecting or improving) of the present invention. The filtrate in step (1) is matter to be removed.

Claims 6, 16, 24, 31, 38 and 50 are rejected under 35 U.S.C. §102(e) as anticipated by Konishi (U.S. Patent No. 6,541,041, of record). In this regard, the Examiner notes these claims are to materials, not processes, and it is incumbent upon Applicants to show that the subject matter of the claims distinguishes Konishi either physically or by function.

In response, as seen above, these claims are now rewritten as method claims, in order to reduce the issues. Additionally, in all claims the family *Saxifragaceae* therein is restricted to the genus *Hydrangea*.

As the Examiner is aware, Konishi teaches a method for extracting soluble silicon compounds from *Saxifraga stolonifera* using water, ethanol or a mixed solution thereof.

However, Konishi does not teach (1) extracting a plant of the genus *Hydrangea* with an aqueous medium and filtering the resulting extract to obtain an extract residue, and (2) extracting the extract residue with alcohol or water containing alcohol to obtain an extract having liver function protecting or improving properties.

Claims 30, 37, 43, 44, 49, 55, 56 and 58 are rejected under 35 U.S.C. §103(a) as being unpatentable over Yamahara (XP 002220391) in combination with Levinson (U.S. Patent No. 6,479,545), both of record.

Of course, claims 30, 49, 55, 56 and 58 are deleted.

The invention of claims 37 and 43 is a method for protecting liver function from damage from excessive intake of alcohol, or for improving liver function impaired from intake of alcohol. The method is characterized in that an effective amount of an extract obtained by the following process¹ is administered to a human or an animal: (1) extracting a plant of *Hydrangea macrophylla* Seringe var. Thunbergii Makino or *Hydrangea Dulcis Folium* or a plant of the genus *Hydrangea* with a aqueous medium and filtering the resulting extract to remove the filtrate and obtain an extract residue, and (2) extracting the extract residue with alcohol or water containing alcohol to obtain and extract.

Yamahara teaches that phyllodulcin, which is a component of the crude drug, *Hydrangeae Dulcis Folium*, has an activity of inhibiting lipid peroxidation. Yamahara does not teach or suggest any method for, e.g., protecting liver function from excessive alcohol intake. This deficiency is not overcome by Levinson, which teaches compositions that provide improved nutritional support for pre-menopausal and menopausal women and/or relief from symptoms associated with menopause.

¹ In this regard, the Examiner states (page 5) “Applicant has not isolated a specific compound from the extracts.” However, such is not required under U.S. practice. Additionally, while the Examiner sees no unexpected results from a two-step extraction, the fact is it was unexpected any effective compounds would remain from an ethanol extraction.

Claims 6, 16, 24, 31, 38, 43, 44, 52-55 and 57 are rejected as being obvious over Fuji Rebio (XP002220392, of record) in combination with Konishi. Claims 52-55 and 57, of course, are deleted.

Fuji Rebio teaches that tannins are obtained by purification using plant species such as *Garanium napalense*, *Saxifraga stolonifera*, and *Eugenia caryophyllata* and that tannins are useful for treating disorders caused by hepatitis B virus. However, Fuji Rebio does not teach or suggest any method for, e.g., protecting liver function from excessive alcohol intake. This deficiency is not overcome by Konishi, which teaches a method for extracting soluble silicon compounds from *Saxifraga stolonifera* using water, ethanol or a mixed solution thereof.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 6, 16, 24, 31, 37, 38, 43, 44 and 50 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



Lawrence S. Perry
Attorney for Applicants
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

LSP\ac

NY_Main 525863_1